

DATE:25/May/1999

SUBJECT: EP [X] MP [] PRODUCT CHEMISTRY REVIEW --ACTION:100
DP BARCODE No.:D253857 REG./File Symbol No.63588-Q
PRODUCT NAME: BASELINE PLANT REGULATOR
COMPANY: K-I CHEMICAL U.S.A. INC.

TO: PM 22; Cynthia Giles-Parker/Thomas Ellwanger, Ph.D.
Branch: Fungicide
Registration Division (H7505C)

FROM: Harold Podall, Ph.D./Chemist *H. Podall*
TRB/RD(7505C)

INTRODUCTION\DESCRIPTION OF SUBMISSION:

Review the product Label, CSF and product chemistry contained in MRIDs 444577-19, -20c, -21 and -22 for registration of the new reduced risk end-use product BASELINE PLANT REGULATOR, containing the active ingredient Prohexadione calcium, for use on peanuts and pome fruit.

SUMMARY OF FINDINGS:

1. The product Label value for the conc. of the active ingredient of 75.0% agrees with the calculated nominal conc. for the active ingredient in the CSF, i.e. $(91\% \text{ purity}/100) \times 82.42\% = 75\%$, and is in concurrence with PR Notice 91-2.

2. The technical for the active ingredient Prohexadione calcium was reviewed by this reviewer on 5/18/99 (D253852).

3. The chemical name for the active ingredient should be simplified to the more readily recognizable name (to chemists in the U.S.A.) of the following:

calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate

4. The certified limits for the nominal concentration of the active ingredient are in concurrence with the Table of Standard Certified Limits in 40 CFR 158.175(b)(2).

5. All of the inert ingredients appear to be cleared for food use and exempt from a tolerance as per 40 CFR 180.1001(c) and/or (d). This is being confirmed with Linda Fan. If I hear otherwise, I will send you a memo on this by 6/2/99.

6. The physical/chemical property data requirements were all met (contained in MRIDs 444577-21 and -22), and the results appear to be technically reasonable.

CONCLUSIONS/RECOMMENDATIONS:

Except for item 3 above under the Summary of Findings, the product Label(from a chemistry standpoint), the CSF and the product

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chemistry requirements have all been satisfied and are technically acceptable. The detailed chemistry report follows.

EP [X] MP [] PRODUCT CHEMISTRY REVIEW

1. Registration [X] 2. Reregistration [], Rereg Case No. _____
3. Pesticide Type: a. Fungicide [] b. Herbicide []
c. Insecticide [] d. Rodenticide [] e. Antimicrobial []
f. Plant Growth Regulator [X] g. Others: _____
4. Uses: a. Food [X] b. Non food use []
5. Type of Submission: New [X] Resubmission [] Amendment []
"ME-TOO" [] Alternate Formulation [] Repack []
Experimental Use Permit [] Other (Specify) _____
6. If "Me-TOO" Registration, this product is [] is not []
similar or substantially similar to EPA's Reg. No.: _____,

If not, comment in Confidential Appendix A on the differences
between the registered and the new source where significant.
7. Information to be reviewed:

a. CSF [X]: Basic [X] Alternate []
b. Label [X] c. Product Chemistry [X]

CONFIDENTIAL STATEMENT OF FORMULA, DATED 10/ 31/1997 :

8. Type of formulation and the sources of active ingredients:
 - a. Non-integrated formulation system.....[X]
 - b. Are all technical grade active ingredients used
registered? • yes [] • no [X]*
The technical is in the process of being registered (see
chemistry review dated 5/18/99, D253852).
 - c. Integrated formulation system.....[]
9. Basic Properties:
 - a. Physical state at ambient temperature: extruded solid
granules
 - b. Density (or bulk density for solids)/temperature:
0.637 g/cc (packed bulk density)
0.579 g/cc(free fall bulk density) --each at 23.7deg.C

c. pH of product:
6.18 (for a 1% disp. in water) at 23 deg.C

d. Flash point (or flame extension for aerosols):
N/A for a solid

10. Composition: The nominal concentrations (NC) of the active ingredients and the upper and lower certified limits (UCL & LCL) are as follows:

Active Ingredient(s)	% by weight		
	NC	UCL	LCL
Calcium 3-oxido-5-oxo-4-propionyl-cyclohex-3-enecarboxylate	75.0	77.3	72.8

11. The calculated NCs, based on the pure active ingredients (PAI), are identical to those on the label:

• yes [X] • no []

12. The certified limits are within the standard limits as per 40CFR§158.175 or are adequately explained if different:

• yes [X] • no []

13. Clearance of intentionally added ingredients in the formulation for the intended use:

a. Formulation intended for food use under 40CFR§180.1001:

• yes [X] • no [] • Some are cleared, others are not []

• Cleared under list: • c [X] • d [X] • e []

• Are there any limitations for use as an inert under 40CFR§180.1001?

• yes [] • no [X], If yes, specify: _____

b. Formulation intended for non-food use:

• yes [] • no [X] • Some are cleared, others are not []

c. Clearance by the FDA of certain formulations under 21CFR §170 to 199.

• yes [] • no [] • Some are cleared, others are not []

If yes, the entire formulation is cleared under 21CFR§__

14. For products produced by an integrated formulation system:
- All impurities of toxicological significance have an UCL:
 - yes []
 - no []
 - not applicable [X]
 - All other impurities > 0.1% associated with the active ingredient in the product are reported at their nominal concentrations:
 - yes []
 - no []
 - not applicable [X]

PRODUCT LABEL, EPA RECEIVED / /199 :

15. The active ingredients statement(chemical identities*, nominal concentrations) is consistent with the CSF • yes[X] • no []
* please note suggested change in name under Summary of Findings, item 3
16. The formulation contains one of the following:
- 10% or more of a petroleum distillate: • yes [] •no [X]
 - 1% or more of methyl alcohol: • yes [] •no [X]
 - sodium nitrite at any level: • yes [] •no [X]
 - a toxic List 1 inert at any level: • yes [] •no [X]
 - arsenic in any form: • yes [] •no [X]
17. If yes to any of the above, does the inert ingredients statement contains a footnote indicating this?
- yes []
 - no []
 - not applicable [X]
18. The appropriate physical and chemical hazards statement regarding flammability or explosive characteristics of the product are given on the label:
- yes []
 - no []
 - not applicable [X]
19. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses:
- yes []
 - no []

PRODUCT CHEMISTRY DATA (SERIES 61 and 62)

<u>20. Chemical IDs/Manufacture/ Analytical Information</u>		<u>Data Required Fulfilled</u>	<u>MRID No.</u>
61-1	Chemical Identity	fulfilled	444577-19
61-2	Starting Materials & Manufact or Formulation Process	fulfilled	444577-19
61-3	Discussion of Impurities	fulfilled	444577-19
62-1	Preliminary Analysis	N/A	
62-2	Certified Limits	fulfilled	444577-20c
62-3	Enforcement Analytical Method	fulfilled (described under storage stability study)	444577-22

PRODUCT CHEMISTRY DATA (SERIES 63)

<u>21. Physical/Chemical Properties</u>		<u>Data Required Fulfilled</u>	<u>Value or Qualitative Description</u>	<u>MRID No.</u>
63-3	Physical State	fulfilled	solid granules	444571-21
63-7	Density/Bulk Density at 23.7 deg.C	fulfilled	0.637 g/cc (packed) 0.579 g/cc (free fall bulk density)	444571-21
63-12	pH of Product	fulfilled	6.18 (1 % disp. in water) at 23 deg.C	444571-21
63-15a	Flammability-Flash Point	N/A		
63-15b	Flame Extension	N/A		
63-16	Explosability	N/A	not considered explosive based on composition	444577-21
63-17	Storage Stability	fulfilled	stable for at least a year.	444577-22
63-18	Viscosity	N/A		

63-19	Miscibility (With Hydrocarbon solvents)	N/A		
63-20	Corrosion Characteristics	fulfilled	no degradation of packing material was seen over a period of a year	444577-22
63-21	Dielectric Breakdown Voltage	N/A		

Explanations: Y = The Requirements Were Fulfilled; N = The Requirements Were Not Fulfilled; NA = Not Applicable; G = Data Gap; U = Requires Upgrading; I = Incomplete or In Progress; W = Waived.